K090525

JUN - 1 2009

510(k) Summary
LOI System

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: February 24, 2009

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: LOI System

COMMON/USUAL NAME: Light Based System

CLASSIFICATION NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology
(21 CFR §878.4810)

PRODUCT CODE: OHS, GEX

3. PREDICATE DEVICES

Photo Therapeutics, Inc.
Omnilux New-U™
K072459

Light Biosciences, LLC
GentleWaves® Consumer LED Photomodulation Device
K062991

Reliant Technologies, Inc.
Fraxel Laser System (Fraxel SR1500, Re:store™)
K070284

4. INTENDED USE

The LOI System is an over-the-counter device intended for treatment of periorbital wrinkles.

5. DEVICE DESCRIPTION

The LOI System is composed of a handpiece, base, power cord, charger, and pre-treatment gel.

6. PERFORMANCE & CLINICAL DATA

The device complies with the following U.S. Food and Drug Administration performance standards: 21 CFR §1040.10 & 1040.11. Clinical data was collected in multiple studies to support the safety and effectiveness of the LOI System for over-the-counter use. The clinical studies demonstrated that the LOI System functions as intended and within an acceptable safety profile.

7. SUBSTANTIAL EQUIVALENCE

The LOI System is substantially equivalent to its predicate devices when intended for use for treatment of periorbital wrinkles. The data in this 510(k) notification demonstrate that the LOI System shares the same intended use, similar design features and functional features, and therefore is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2009

Palomar Medical Products, Incorporated
% Ms. Sharon Timberlake
82 Cambridge Street
Burlington, Massachusetts 01803

Re: K090525
Trade/Device Name: LOI System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery And in Dermatology
Regulatory Class: II
Product Code: ONG
Dated: April 24, 2009
Received: April 27, 2009

Dear Ms. Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

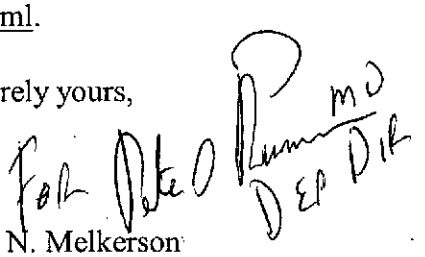
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: LOI System

Indications for Use:

The LOI System is an over-the-counter device intended for treatment of periorbital wrinkles.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090525